DEPARTMENT OF HEALTH & HUMAN SERVICES

RB 9/2/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

September 2, 1999

WARNING LETTER

Graham J. O'Neall, Chief Executive Officer
Heart of the Ozarks Medical Equipment
#7 Parkway Center
West Plains, MO 65775

KAN #99-026

Dear Mr. O'Neall:

Recently an inspection was made of your medical oxygen transfilling operation, located at the above address. This inspection was conducted on July 20, 1999, by Food and Drug Administration Investigators from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the medical oxygen transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

- failure to verify that lot numbers being used on filled cylinders of compressed medical gas match the lot number on the batch production record, and failure to follow your standard operating procedure (SOP) for applying lot numbers [21 CFR 211.130(c)];

- failure to establish that the test procedure used to determine the purity of the medical oxygen will provide test results that are equivalent or superior to the official test procedure. Example – the [redacted] handheld oxygen analyzer is only sensitive to +/- 2% [21 CFR 211.165(e)];

- failure to perform adequate prefill operations on each high pressure cylinder [21 CFR 211.84(d)(3)];

- failure to remove from filled cylinders of medical oxygen labels that are damaged, illegible, or more than one [21 CFR 211.122 & 211.125].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the conclusion of the inspection a Form FDA 483, List of Observations, was issued to and discussed with, Ms. Joann Strosnider, Manager. A copy of this form is enclosed for your information.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your compressed medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

By copy of this letter, we are advising the Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure – Form FDA 483